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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
09/811,360	03/16/2001	Eugene M. Wolf	2502440-991501	7725
29585	7590	10/06/2004		EXAMINER
				BLANCO, JAVIER G
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

M/

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/811,360	WOLF, EUGENE M.	
<b>Examiner</b>		<b>Art Unit</b>	
Javier G. Blanco		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 July 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4-25,28-39,41-43,50-52,54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 4-25, 28-39, 41-43, 50-52, 54, and 55 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendment of independent claims 1, 8, 16, 23-25, 31, 42, 43, 50, and 54 in the reply filed on July 14, 2004 is acknowledged.
2. Applicant's cancellation of claims 3, 7, 27, 40, and 53 in the reply filed on July 14, 2004 is acknowledged.
3. With regards to Amendment G (Paper # 27; filed January 07, 2004) and the current amendment (filed July 14, 2004), the Examiner noticed that claims 44-49 are indicated as being "withdrawn". Examiner respectfully disagrees. As seen in Amendment C (Paper # 12; filed October 8, 2003), these claims were previously cancelled. This was addressed in the previous office action.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1, 4-6, 8-25, 28-39, 41-43, 50-52, 54, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - a. With regards to independent claims 1, 8, 16, 23-25, 31, 42, 43, 50, and 54, new claim limitation "non-intramedullary base extension" lacks antecedent basis. Claims 4-6, 9-15, 17-22, 28-30, 32-39, 41, 51, 52, and 55 depend on claims 1, 8, 16, 23-25, 31, 42, 43, 50, and 54.
  - b. With regards to claim 6, it depends on a cancelled claim (= claim 3).

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- c. With regards to claim 43, new claim limitation “including cement or ingrowth fixation, or both, of the humeral head with the humeral surface” (see lines 9-10) is vague and confusing, rendering the whole claim indefinite.
- d. With regards to claim 50, new claim limitation “including cement or ingrowth fixation, or both, of the humeral head with the humeral surface” (see lines 10-11) is vague and confusing, rendering the whole claim indefinite.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 4-25, 28-39, 41-43, 50-52, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinnet (US 4,550,450 A; cited in Applicant's IDS) in view of Masini (US 5,571,203 A; cited in Applicant's IDS), Swanson et al. (US 4,042,980 A; cited in Applicant's IDS), and Chiron-Werke (DE 1164019; cited in Applicant's IDS).

As seen in Figures 1, 2, 5, and 6, Kinnet discloses a total shoulder arthroplasty apparatus comprising a stemless, partial humeral head fixation (humeral component 10) for coupling to a cut humeral surface (see Figure 1), wherein the partial humeral head fixation includes a partial humeral head (main body portion 20) including a base surface (= root or base wall) and a rotationally-stabilizing (see column 4, lines 40-42) base extension (fixation post/keel 21) protruding therefrom for impaction into a cancellous region of the cut humeral surface (see

Figure 1; see entire document). Kinnett also discloses the claimed method of implanting the total shoulder arthroplasty apparatus (see columns 5-7). Kinnett further discloses the use of a template punch (see column 6, lines 40-51). The base extension is impacted and non-intramedullary (see column 7, lines 13-27; see entire document).

Although Kinnett shows the fixation post/keel 21 as having a slight depression (see Figure 1) and also that the fixation post/keel “provides increased mechanical advantages against torque and provides increased surface area of fixation” (see column 4, lines 40-42) and also that it prevents dislocation (see column 4, lines 50-53), he/she does not particularly disclose the base extension as including a plurality of fins.

a. Masini ‘203 teaches a prosthetic orthopedic device (see Figures 3-6) comprising a base extension including a plurality of fins (fins 310) in order to limit or prevent the rotational motion of the prosthetic orthopedic device relative to the anchor area/site (see column 4, lines 35-53). Masini also discloses that this plurality of fins (also referred to as anti-rotation means) “may be employed, or used in conjunction with a number of other bone-engaging orthopedic devices to prevent rotation” (see column 4, lines 51-53). Therefore, it would have been obvious to a person of ordinary skill in the art to have combined the teaching of a base extension including a plurality of fins, as taught by Masini, with the prosthetic orthopedic device of Kinnett, in order to limit or prevent the rotational motion of the prosthetic orthopedic device relative to the anchor area/site (i.e., cut humeral surface).

b. Masini ‘203 teaches several species of anti-rotation means such as: one or more fins, curved fins, posts, and so forth (see column 4, lines 48-53). Masini is evidence of the use of different species of anti-rotation means for a prosthetic orthopedic device. Therefore, it would have been

obvious to a person of ordinary skill in the art to have used multiple fins with Kinnett's base extension (= fixation post/keel 21) since, in view of the teachings of Masini, anti-rotation means shaped as one or more fins, curved fins, posts, and so forth, are functionally equal and interchangeable.

Kinnett does not disclose the fixation keel 21 as been linear. However, Swanson et al. and Chiron-Werke teach at least one linear fin extending from the base of the prosthetic orthopedic device in order to anchor the prosthetic orthopedic device and prevent or limit rotational motion of it relative to the anchor area/site (see Swanson et al.'s column 3, lines 3-8; see Chiron-Werke entire document). Therefore, it would have been obvious to a person of ordinary skill in the art to have combined the teaching of at least one linear fin extending from the base of the prosthetic orthopedic device, as taught by Swanson et al. and Chiron-Werke, with the prosthetic orthopedic device of Kinnett, in order to anchor the prosthetic orthopedic device and prevent or limit rotational motion of it relative to the anchor area/site (i.e., cut humeral surface).

#### ***Response to Arguments***

8. Applicant's arguments filed July 14, 2004 have been fully considered but they are not persuasive.

Applicant argues that the "substantially uniformly planar, intersecting fins" is not taught or suggested by any of the cited references. Examiner respectfully disagrees. Merriam-Webster dictionary defines "intersect" as: "to meet and cross at a point". As seen in Masini '203 Figure 3, the cruciform-shaped plurality of fins 310 meet and cross at the bottom of bullet-like feature 228

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(see column 4, lines 35-43 and lines 55-57). Any of the different anti-rotation means species discloses in Masini '203 will provide rotational stabilization to the system in relation to the bone.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

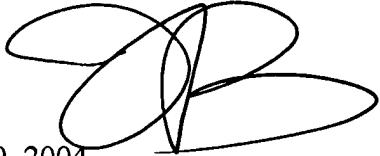
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



September 30, 2004



David H. Willse  
Primary Examiner